

REMARKS/ARGUMENTS

By this Amendment, claim 3, 12-18 and 19-20 are canceled; claims 1, 4 are amended. Claims 1-2, and 4-11, are pending.

Citations to the Specification are directed to U.S. Patent Application Publication No. 2005/0182114 (Parthasaradhi). Support for the amendment to claim 1 can be found throughout the Specification as filed, and specifically in claim 3 (canceled herein).

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Entry of this Amendment is proper under 37 C.F.R. §1.116 because the Amendment: (a) places the application into condition for allowance (for reasons discussed herein), (b) does not raise any new issues requiring further search and/or consideration (because the Amendment is directed to subject matter previously considered during prosecution), (c) does not present any additional claims without canceling a corresponding number of finally rejected claims, and (d) places the application into better form for appeal, should an appeal be necessary. Applicants respectfully request entry of the Amendment.

Objection to the Claims

The Examiner has rejected claims 3-11 as being dependent on rejected claim 1. This objection is respectfully traversed.

Here, claim 1 has been amended to be directed to candesartan cilexetil 1,4-dioxane solvate, characterized by an x-ray powder diffraction pattern having peaks expressed as 2θ at about 6.0, 10.7, 16.2, 18.0, 19.7, 20.6, 21.3, 21.7, and 22.3 degrees, which are the limitations from claim 3, which the Examiner has indicated as being allowable. Claim 3 has been canceled

herein.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 USC 112, first paragraph

Claim 19 stands rejected under 35 USC 112 first paragraph. This rejection is respectfully traversed.

However, without acquiescing to the propriety of the Examiner's rejection, and solely in an effort to advance prosecution, claim 19 has been canceled herein. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 USC 103(a)

Claims 1-2 stand rejected under 35 USC 103(a) as being unpatentable over Naka et al. U.S. Patent No. 5,196,444 in view of publication of U.S. Department of Health and Human Service, Guidance for Industry, May 15, 2001. This rejection is respectfully traversed.

The claims are patentable over the combination of US 5,196,444 in view of publication of U.S. Department of Health and Human Service, Guidance for Industry for the following reasons. The framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows: (A) Determining the scope and content of the prior art; and (B) Ascertaining the differences between the claimed invention and the prior art; and (C) Resolving the level of ordinary skill in the pertinent art. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). "All words in a claim must be considered in judging the patentability of

that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). MPEP 2143.03. It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

Here, claim 1 has been amended to be directed to candesartan cilexetil 1,4-dioxane solvate, characterized by an x-ray powder diffraction pattern having peaks expressed as 2θ at about 6.0, 10.7, 16.2, 18.0, 19.7, 20.6, 21.3, 21.7, and 22.3 degrees. As the Examiner admits, the Naka et al. patent does not teach or suggest the instant polymorph of candesartan cilexetil 1,4-dioxane.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

* * *

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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